DEC - 8 2003

K032812

1 of 2

510(K) SUMMARY FOR THE ORTHOVITA, INC. ENDOSKELETON TA VBR

Submitter's Name, Address, Telephone Number, And Contact Person

Orthovita, Inc.
45 Great Valley Parkway
Malvern, PA 19355
Contact: David McIlhenny
Telephone: (610) 407-5211
Facsimile: (610) 640-2603

Date Prepared

September 4, 2003

Name of the Device

Endoskeleton TA Vertebral Body Replacement

Common or Usual Name

Vertebral Body Replacement

Classification Name

Vertebral Body Replacement (MQP)

Predicate Devices

- DePuy Acromed Stackable Cage (K990148, K013382)
- Synthes Vertebral Spacer *Ti* (K020152, K024364)

Intended Use

The Endoskeleton TA VBR is for use in the thoracolumbar spine (T1-L5) to replace all or part of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (*i.e.*, fracture). The Endoskeleton TA VBR is intended for use with supplemental internal spinal fixation systems. The Endoskeleton TA VBR may be used with bone graft material or bone graft substitute.

Principles of Operation

The principles of operation of the modified device are identical to the other previously cleared VBR systems. Like the predicate VBRs, the Endoskeleton TA VBR is inserted in the spine together with supplemental internal spinal fixation. Bone graft material may be placed in and/or around the implant. One implant is inserted per spinal level via an anterior surgical approach.

Technological Characteristics

The Endoskeleton TA VBR is a titanium implant that is oval in shape. The implant is available in a range of sizes in 0-7° lordotic angles, higher in the anterior than the posterior, to restore spinal lordosis. The center of the implant is hollow and can be filled with bone graft material. The device is available in a range of sizes to accommodate the individual patient's anatomic space. The surface of the implant is roughened to improve stability and resistance to expulsion. A set of customized instruments will be provided for use with the Endoskeleton TA VBR to facilitate its implantation.

Summary Basis for the Finding of Substantial Equivalence

The Endoskeleton TA VBR described in this submission has same intended use and very similar indications for use and technological features to a number of other previously cleared VBR devices. The implantation procedure for the Endoskeleton TA VBR also is substantially similar to other currently available VBRs. Any minor differences between the Endoskeleton TA VBR and the predicates do not raise any new types of safety or effectiveness issues, and performance data in the submission demonstrate that these differences do not adversely impact its safety or effectiveness. Therefore, the Endoskeleton TA VBR is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2003

Mr. David McIlhenny
Senior Vice President, Operations
Orthovita, Inc.
45 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K032812
Trade/Device Name: Orthovita Vertebral Body Replacement
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: September 5, 2003
Received: September 9, 2003

Dear Mr. McIlhenny:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.41

Indications for Use Statement

510(k) Number (if known): K032812

Device Name: Orthovita Vertebral Body Replacement

Indications for Use:

The Endoskeleton TA VBR is for use in the thoracolumbar spine (T1-L5) to replace all or part of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (*i.e.*, fracture). The Endoskeleton TA VBR is intended for use with supplemental internal spinal fixation systems. The Endoskeleton TA VBR may be used with bone graft material or bone graft substitute.

for Mark N Milkins

Division Sign-Off
Division of General, Restorative and Neurological Devices

510(k) Number K032812

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)